UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MASS DYNAMICS, LLC, BOSTON VAPOR, LLC, LINDA AND JEFFREY VICK d/b/a VICK'S VAPE SHOP, JIMBUDDY'S INCORPORATED, and, JERALD MOLLMAN d/b/a J'S VAPOR DEN, Plaintiffs, v. CHARLES D. BAKER, in his official capacity as GOVERNOR OF THE COMMONWEALTH OF MASSACHUSETTS, MONICA BHAREL, M.D., in her official capacity as DEPARTMENT OF PUBLIC HEALTH COMMISSIONER, and COMMONWEALTH OF MASSACHUSETTS, Defendants.	)	CIVIL ACTION NO. 19-12035 VERIFIED AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

INTRODUCTION

Plaintiffs Mass Dynamics, LLC ("Mass Dynamics"), Boston Vapor, LLC ("Boston Vapor"), Linda and Jeffrey Vick doing business as Vick's Vape Shop ("Vick's"), JimBuddy's Incorporated ("JimBuddy's"), Jerald Mollman doing business as J's Vapor Den ("Vapor Den") (collectively, the "Plaintiffs"), by their undersigned counsel, hereby bring this Verified Amended Complaint against Defendants Charles D. Baker, solely in his official capacity as Governor of the Commonwealth of Massachusetts ("Governor Baker"), Monica Bharel, M.D., solely in her official capacity as Commissioner of the Department of Public Health ("Commissioner Bharel"), and the Commonwealth of Massachusetts (the "Commonwealth") (collectively, the "Defendants"), and state and allege the following:

1. This is an action seeking temporary, preliminary and permanent injunctive relief, a declaratory judgment, and other appropriate relief to set aside as unconstitutional the recent actions of the Defendants to ban the sale of electronic cigarettes, vapes, vaporizers, vape pens, hookah pens, e-pipes and related products and components thereof – known as electronic nicotine delivery systems ("ENDS") – in addition to so-called "e-liquids," which have been deemed safe and effective for marketing and use in the United States by the Food and Drug Administration ("FDA"), and are regulated by the FDA.

2. The FDA regulates ENDS products pursuant to its authority set forth in the Tobacco Control Act ("TCA") and the Food, Drug, and Cosmetic Act ("FDCA").

3. The "e-liquid" used in connection with many ENDS products may contain nicotine, as well as varying compositions of flavorings, propylene glycol, vegetable glycerin, and other ingredients. They do not include Vitamin E additives. The liquid is heated to create an aerosol that the user inhales.

4. Notwithstanding that the FDA already has determined that the products sold by the Plaintiffs are approved for marketing and sale in the United States, Governor Baker recently issued an "emergency declaration" (the "Declaration") empowering Commissioner Bharel to issue an order prohibiting the sale of electronic cigarettes and related products and the components thereof (the "Ban"), including but not limited to related signage (the "Signage Regulation"). The Ban on the entire class of products will only be lifted "[u]pon declaration by the governor that such emergency has terminated." See G.L. c. 17, § 2A.

5. When the FDA issued rules and regulations relative to ENDS it rejected the idea of an outright ban on the entire class of electronic cigarettes and related products.

PARTIES

6. Plaintiff Mass Dynamics is a Massachusetts limited liability company, whose Manager is Behram Agha, with its principal place of business at 331 Front Street, Weymouth, Massachusetts. Mass Dynamics only sells electronic cigarettes and related products.

7. Plaintiff Boston Vapor, LLC is a New Hampshire limited liability company, whose Manager is Mike Chance, and whose Registered Agent is Dena Chance, with its principal place of business located at 9 Leonard Lane, Salem, New Hampshire. Boston Vapor markets and sells ENDS products.

8. Plaintiffs Linda and Jeffrey Vick doing business as Vick's Vape Shop maintain a principal place of business at 466B Salem Street, Medford, Middlesex County, Massachusetts. Vick's markets and sells ENDS products.

9. Plaintiff JimBuddy's Incorporated is a Massachusetts corporation that maintains a principal place of business at 1271 Memorial Drive, Chicopee, Massachusetts. James M. Robinson is the President of JimBuddy's. JimBuddy's markets and sells ENDS products.

10. Plaintiff Jerald Mollman doing business as J's Vapor Den is a Massachusetts business entity that maintains a principal place of business at 679 Washington Street, Attleboro, Massachusetts.

11. Defendant Charles D. Baker is the Governor of the Commonwealth of Massachusetts. Governor Baker maintains an office at the Massachusetts State House, Office of the Governor, Room 105, Boston, Massachusetts 02133.

12. Defendant Monica Bharel, M.D. is the Commissioner of the Massachusetts Department of Public Health. Upon information and belief, Commissioner Bharel maintains an office at the Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts, 02108.

13. Defendant Commonwealth of Massachusetts is a body politic. Upon information and belief, the Commonwealth of Massachusetts maintains an office at the State House, Boston, Massachusetts 02133. The Office of the Massachusetts Attorney General ("AGO") is empowered to accept service on behalf of the Commonwealth. The AGO maintains an office at One Ashburton Place, Boston, Massachusetts. The Commonwealth is made a defendant solely for the purpose of imposing an award of attorney's fees pursuant to 42 U.S.C. § 1988.

JURISDICTION AND VENUE

14. Jurisdiction in this Court is grounded upon and proper under 28 U.S.C. § 1331 in that this is a civil action arising under the laws of the United States; and 28 U.S.C. §§ 2201-2202 in that there exists between the Plaintiffs and the Defendants an actual, justiciable controversy as to which the Plaintiffs require a declaration of its rights by this Court as well as temporary, preliminary and permanent injunctive relief to prohibit the Defendants from violating federal laws and regulations and abridging its rights protected under the U.S. Constitution.

15. Venue is proper in this Court under 28 U.S.C. § 1391 (b) because this is a civil action in which the Defendants maintain their offices and conduct business in this judicial district. Moreover, a substantial part of the events giving rise to the claims herein occurred within this judicial district.

16. The Plaintiffs have standing to bring the present lawsuit because Defendants' actions have caused the Plaintiffs actual injury, which is redressable through the specific relief requested herein. As family business owners purchasing and selling ENDS and e-liquids through interstate commerce pursuant to their approval by the FDA, the Plaintiffs' operations also fall within the zone of interests to be protected by the Contract, Equal Protection, and dormant Commerce Clauses of the U.S. Constitution, as well as 42 U.S.C. §§ 1983 and 1988, and general federal preemption principles.

17. This case is ripe for adjudication. As further discussed below, the enforcement of the Declaration and Ban will result in an immediate and concrete invasion of the Plaintiffs' legally protected interests under federal law.

NATURE OF THE CASE

18. This is a civil rights and declaratory judgment action brought pursuant to 28 U.S.C. § 2201, *et seq.* and 42 U.S.C. § 1983 for the purpose of challenging the constitutionality of the Declaration and the Ban.

19. The Plaintiffs challenge the constitutionality of the Declaration and the Ban as violating the Commerce Clause of the United States Constitution with respect to its prohibition against the manufacture, distribution, sale, or offering for sale of flavored e-liquid ENDS products intended for distribution and sale to customers located inside and outside the Commonwealth of Massachusetts.

20. The Plaintiffs seek a declaratory judgment with respect to their respective constitutional claims, and injunctive relief barring the Defendants from enforcing the Declaration and the Ban with respect to the prohibition against the in-state manufacture, distribution, sale and offer for sale of e-liquid ENDS products to customers.

21. The Plaintiffs challenge the constitutionality of the Declaration and Ban as being overbroad in violation of the Fourteenth Amendment to the United States Constitution as applied to them and other similarly situated e-liquid ENDS products retailers in Massachusetts.

22. In addition, the Plaintiffs challenge the constitutionality of the Signage Regulation as violating the First Amendment of the United States Constitution on the basis that impairs the Plaintiffs right to free speech, and as violating the Supremacy Clause of the United States Constitution on the basis that it requires actions by them and other similarly-situated ENDS product retailers located in Massachusetts to place signage in their establishments which convey a message that conflicts with the proscriptions of the applicable federal regulations.

23. The Plaintiffs seek a declaratory judgment with respect to their respective constitutional claims, and injunctive relief barring the Defendants from enforcing the Declaration, the Ban and the Signage Regulation against them and all similarly-situated ENDS product retailers.

ENDS Products

24. The Plaintiffs all operate business enterprises which either manufacture, distribute, or sell ENDS products and related products associated with the open system market segment, as described below, including e-liquids ENDS products.

25. ENDS products are a technology which has been marketed and sold in the United States since approximately 2008. ENDS products are not traditional cigarettes, as they do not use tobacco and there is no combustion or smoke emitted as a result of their use and consumption.

26. Rather, ENDS products produce an aerosol which is created when a lithium battery activates a heating coil (called an atomizer) which in turn results in the vaporization of an e-liquid solution. ENDS products have the same purpose and functional utility – they allow the user to inhale the vapor through a mouthpiece (called "vaping"), with the aerosol providing a flavor and physical sensation similar to that of smoking a cigarette.

27. The stakeholders in the ENDS products industry have segregated themselves into two distinctive segments: the "open system" segment and "closed system" segment.

28. The ENDS products purveyed in the closed system market segment contain a small rechargeable lithium battery that produces a relatively low amount of vapor, and a small, built-in cartridge holding pre-filled and disposable e-liquid cartridges or pods.

29. The closed system ENDS cartridges and pods generally only offer a limited variety of flavor choices. Closed system ENDS products generally require e-liquids which contain a high concentration of nicotine, measured in milligrams per milliliter. This is the case because the batteries used in the products generate a low capacity of power thus requiring e-liquids with a higher nicotine concentration in order to provide a satisfactory consumer experience. Thus, it is common that closed system e-liquid cartridges and pods to contain nicotine concentrations as high as 50 mg/ml, a quantity equivalent to the total nicotine contained in a pack of cigarettes.

30. The following are examples of closed system ENDS products:

31. Simply stated, the closed system ENDS products are akin to one-size-fits-all products which allow consumers little, if any, customization options.

32. In general, closed system ENDS products are manufactured and distributed by legacy tobacco companies such as Altria Group (*MarkTen*® brand), Reynolds American (*VUSE*® brand), and Lorillard Inc. (*Blu*® brand). The most popular closed system ENDS product, by market share, is the *Juul*® brand which manufactured and distributed by Juul Labs, Inc. In late 2018, legacy tobacco company Altria Group purchased a 35% share of Juul Labs, Inc. for approximately $13 billion dollars.

33. The products purveyed in the closed system market segment comprise approximately fifty-eight percent (58%) of the total ENDS products market in the United States.[1]

34. On the other hand, open system ENDS devices are somewhat larger in size and utilize: (a) a higher powered rechargeable lithium battery, either replaceable or self-contained within the device, than their closed system counterparts and (2) an interchangeable and refillable e-liquid tank. When used in conjunction with each other,

[1] The vapor industry is very diverse and complex. Closed-system and pod-based e-cigarettes (like JUUL) make up roughly 57.5% of the $6.6 billion U.S. vapor products market, with open-system vapor products (e.g., tanks, mods, e-liquids, etc.) making up approximately 42.4% in 2018, according to Wells Fargo. See Bonnie Herzog, Nielsen: Tobacco All Channel Data Through 9/8, WELLS FARGO SECURITIES, (Sept. 8, 2018).

these two elements allow open system ENDS devices to produce relatively more vapor than closed system ENDS devices.

35. The following are examples of open system ENDS devices:

and the following are examples of open system ENDS e-liquids:

The "Fountain" e-liquid product depicted above is a brand owned and distributed by

OPMH.

36. Because open system ENDS products generate a greater quantity of power *vis-à-vis* closed system products, they generally require e-liquids which contain a significantly lower concentration of nicotine. Typically, open system e-liquid products contain nicotine in varying concentrations at 3 mg/ml increments ranging from 0 mg/ml to 12 mg/ml.

37. Open system ENDS products exist because to the ingenuity of former closed system ENDS product consumers sought a better vaping experience. The birth and growth of the open system ENDS products market exists as the result of a grassroots movement by the consumers of the first and second generation closed system ENDS products who were not satisfied by their low powered devices and the poor quality of e-liquids which then existed. This resulted in the development of open system ENDS devices and e-liquids designed for use in such devices.

38. These consumers designed and produced competing open system ENDS devices which utilized a more enhanced technology calculated to generate more power. These open system ENDS devices utilize larger, sometimes multiple, re-chargeable lithium batteries, contain computer chips which allow consumers to independently regulate both thermal and wattage parameters and allow consumers to utilize larger atomizers. The result of these technological advances has allowed open system ENDS product consumers to customize their devices.

39. In conjunction with the advent to open system ENDS devices, consumers began experimenting with creating new and better quality e-liquid products for their personal use. The result of this experimentation has been an abundance of thousands of

open system ENDS product e-liquid brands and flavors. If an open-system ENDS product consumer has a particular flavor or taste preference, there is likely an e-liquid to satisfy such preference.

40. The e-liquid products used in both closed system ENDS products and open system ENDS products are manufactured using a mixture of three or four primary ingredients – vegetable glycerin, propylene glycol, flavorings, and liquid nicotine. The purpose of propylene glycol and vegetable glycerin, the base e-liquid ingredients, is mainly to act as a carrier for other ingredients and to produce visible vaporized aerosol when evaporated.[2] The flavorings in e-liquids are the same flavoring agents used in foods or tobacco products, with numerous e-liquid flavors marketed today.

41. The similarities between the e-liquids used in the closed system e-liquid products and open system e-liquid products end there. This is the case because closed system ENDS products and open system ENDS products utilizes a completely different technology with respect to the manner in which e-liquids are delivered and consumed.

42. Closed system e-liquids utilize pre-filled pods or cartridges which are designed to be discarded and replaced upon consumption. Closed system e-liquid products are generally limited to approximately less than twenty (20) flavors and are available only in high nicotine concentrations of a single quantity or two quantities.

43. Further, it is also common that the e-liquids used in closed system cartridges and pods contain benzoic acid in order to enhance the speed of the body's uptake of nicotine.

44. Open system e-liquid products as depicted in Paragraph ___ above, on the

[2] Propylene glycol and vegetable glycerin are classified by the United States Food and Drug Administration ("FDA") and the Flavor and Extracts Manufacturer Association ("FEMA") as additives that are "Generally Recognized As Safe" ("GRAS") for use in food

other hand, are manufactured and sold in bottles of varying sizes and are offered in virtually thousands of flavors.

45. Not surprisingly, the rise in popularity of ENDS products has resulted in a closely corresponding reduction in the consumption and use of traditional combustible tobacco products in the United States. In fact, both the adult and youth smoking rates in the United States are at all-time lows.[3]

Health Benefits Of ENDS Products

46. A large and growing body of scientific evidence indicates that ENDS products, while not completely harmless, do not pose the same harms and health risks, and are substantially less harmful, than traditional combustible tobacco products. This is due in part to the fact that the e-liquids used in ENDS products do not contain tobacco and do not result a combustion process which produces numerous harmful by-products, like the emission of particulate matter (tar) and many other carcinogens and harmful substances.[4]

47. Research further suggests that because e-liquids and the resulting aerosol vapor emitted from the ENDS products in which they are used do not expose the users or those in close proximity to the emission of numerous toxic chemicals found in the smoke of combustible tobacco. As a result, the use of these non-combustible ENDS products is safer than combustible tobacco as a means of nicotine delivery. This is expected to result

[3] See Smoking rate in US hits all-time low, CDC says, CBS News (June 19, 2018) available at <https://www.cbsnews.com/news/smoking-rate-in-u-s-hits-all-time-low/?> (accessed September 27, 2019).

[4] Linda Bauld, *The evidence keeps piling up: e-cigarettes are definitely safer than smoking,* The Guardian (December 29, 2017), <https://www.theguardian.com/science/sifting-the-evidence/2017/dec/29/e-cigarettes-vaping-safer-than-smoking> (accessed September 27,2019).

in a vast reduction in tobacco-related disease and death over time.[5]

48. Moreover, there is considerable evidence that the overwhelming majority of users of ENDS products in the United States, commonly identified as "vapers," are now former cigarette smokers who have turned to the several generations of ENDS products as a smoke-free alternative to reduce or outright quit smoking, and to avoid the significant health hazards associated with combustible tobacco products.[6]

49. In 2018, the National Academies of Science, Engineering and Medicine completed an exhaustive review of the peer-reviewed literature on ENDS products. Such study concluded, in pertinent part, from such literature that:

> "[l]aboratory tests of e-cigarette ingredients, in vitro toxicological tests, and short-term human studies suggest that e-cigarettes are likely to be far less harmful than combustible tobacco cigarettes."[7]

A further review of relevant science completed in 2019 concluded the existence of growing evidence showing that ENDS product emission aerosols are relatively safe compared to combustible tobacco smoke.[8]

50. Mitchell Zeller, the Director of the Food and Drug Administration

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[5] See John Britton, *Electronic cigarettes and the precautionary principle,* The BMJ Opinion (September 20, 2019), <https://blogs.bmj.com/bmj/2019/09/20/john-britton-electronic-cigarettes-and-the-precautionary-principle/> (accessed September 27, 2019).

[6] Paul Blair, *New CDC Data, More Than 9 Million Adults Vape Regularly in the United States,* Americans for Tax Reform (November 9, 2015), <https://www.atr.org/new-cdc-data-more-9-million-adults-vape-regularly-united-states> (accessed September 27, 2019).

[7] See National Academies of Science, Engineering and Medicine: Committee on the Review of the Health Effects of Electronic Nicotine Delivery Systems, THE PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES (Kathleen Stratton *et al.* eds., 2018), available at <https://tinyurl.com/ya4w37kb> (accessed September 27, 2019).

[8] Riccardo Polosa et al., (2019). The effect of e-cigarette aerosol emissions on respiratory health: a narrative review, Expert Review of Respiratory Medicine, <https://www.tandfonline.com/doi/full/10.1080/17476348.2019. l649146> (accessed September 27, 2019)

("FDA") Center for Tobacco Products, recently acknowledged in sworn testimony in another federal court proceeding that some ENDS products may reduce harm and help some addicted smokers end combustible tobacco use. Director Zeller further noted in his sworn testimony that "[d]ramatically and precipitously reducing availability of [vapor] products" in the fashion embodied in the Emergency Regulated "could present a serious risk that adults, especially former smokers, who currently use [ENDS] products and are addicted to nicotine would migrate to combustible tobacco products"[9]

51. Public health authorities around the world have come to similar conclusions. In April 2016, the British Royal College of Physicians ("RCP"), the world's oldest professional medical society, authored and issued a report lauding the benefits of ENDS products as safer alternatives to combustible tobacco (the "RCP Report"). The RCP Report summarizes the science, public policy, regulation, and ethical issues related to ENDS products and concludes that utilizing such products is not a "gateway" to smoking. On the contrary, the RCP Report concluded that "the available evidence to date indicates that [ENDS products] are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely."[10]

52. Specifically, the RCP Report estimates that ENDS products are only 5% as harmful as combustible tobacco products and that the long-term effects of nicotine

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[9] Declaration of Mitchell Zeller, American Academy of Pediatrics v Food and Drug Admin, No 8:18-cv-00883-PWG (D. Md. 2019) at 115, available at <https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/wysiwyg/Zeller%20Declaration%2C%206-12-l 9.pdf> (accessed September 27, 2019).

[10] Royal College of Physicians, *Nicotine without smoke: Tobacco harm reduction,* Report (April 28, 2016), available at <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0> (accessed September 27, 2019).

from aerosolized vapor are likely to be minimal. This estimate corresponds with the conclusions of Public Health England, a department of the British Government, which determined that, based on the current evidence, ENDS products are at least 95% less harmful than combustible tobacco products.[11]

53. Both the RCP Report and Public Health England study show that a growing number of scientific and public health experts in the United States and around the world agree that the use of ENDS products is significantly less harmful than smoking combustible tobacco products and a valuable tool for tobacco harm reduction efforts for adult tobacco users.

Federal Regulation Of Ends Products

54. The FDA first began regulating ENDS products in the same manner as traditional tobacco products (*e.g.*, cigarettes) in May 2016 upon the publication of what is colloquially known as the "Deeming Rule" to be effective on August 8, 2016.

55. The Family Smoking Prevention and Tobacco Control Act (the "TCA") initially charged the FDA with regulating "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." In addition, the TCA delegated authority[12] to the FDA to regulate "any other tobacco products that [the FDA] by regulation deems to be subject to this chapter."[13]

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[11] Royal College of Physicians, *Nicotine without smoke: Tobacco harm reduction,* Report (April 28, 2016), available at <https://www.rcplondon.ac.uk/projects/ outputs/nicotine-without-smoke-
tobacco-harm-reduction-0> (accessed September 27, 2019).

[12] The constitutionality of Congress' delegation of deeming authority to the FDA is presently at issue in Big Time Vapes, Inc. vs. Food and Drug Admin, No 1:19-cv-00531-HSO-JCG (D. Miss. 2019).

[13] 21 USC § 387a(b).

56. Effective August 8, 2016, the FDA invoked this deeming authority to extend the TCA's requirements to ENDS products that contain or are intended to be used with tobacco-derived ingredients such as nicotine.[14]

57. Because of the Deeming Rule, all ENDS products are now subject to, among other regulations:

a. Prohibitions on the sale of adulterated or contaminated tobacco products;[15]

b. Prohibitions on the sale of misbranded tobacco products;[16]

c. Requirements that manufacturers submit health information (*e.g.*, health studies, ingredient reports) regarding each tobacco product;[17]

d. Requirements that manufacturers register their production facilities with the FDA;[18]

e. Restrictions on advertising the sale and distribution of tobacco products;[19]

f. Promulgated good manufacturing practices;[20]

g. Tobacco product standards *(e.g.*, flavor restrictions) adopted through notice-and-comment rulemaking;[21]

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[14] 81 Fed Reg at 28,975.

[15] 21 USC § 387b.

[16] 21 USC § 387c.

[17] 21 USC § 387d.

[18] 21 USC § 387e.

[19] 21 USC § 387f(d).

[20] 21 USC § 387f(e).

[21] 21 USC § 387g(a).

h. Requirements that manufacturers establish and maintain records;[22] and

i. Prohibitions on manufacturers and retailers distributing free samples of tobacco products, except free samples of smokeless tobacco (*i.e*., chewing tobacco), which may be distributed in "qualified adult-only facilities."[23]

58. As a result of the Deeming Rule, ENDS product manufacturers must submit substantial information to the FDA, including scientific research findings on the ability of the products to reduce risk or exposure, data and information on how consumers actually use the products, and post-market surveillance studies. The ENDS product manufacturers must also demonstrate that there is a significant reduction in risk of tobacco-related disease and the FDA must take into account, on a population level, the health benefit to users of tobacco products and those who do not use such products (the "public health benefit" standard).[24]

59. The TCA also requires ENDS product manufacturers of any "new tobacco product" to obtain pre-market authorization prior to commercial sale. The TCA defines a "new tobacco product" to mean, in part, "any tobacco product ... that was not commercially marketed in the United States as of February 15, 2007," known as the Grandfather Date. 21 U.S.C. § 387j. Any tobacco product that was on the market as of the Grandfather Date is exempt from the FDA pre-market review requirements.[25]

60. There are no grandfathered ENDS products, and the entire product category is considered "new" and thus subject to the FDA premarket review requirements

[22] 21 USC § 387(i).

[23] 21 USC § 387a-1(a).

[24] 21 USC § 387k.

[25] 21 USC §§ 387eG), 387j(a).

set forth in the TCA. For deemed tobacco products on the market as of August 8, 2016, however, the Deeming Rule established a "compliance policy" permitting such products to remain on the market for a period of time before premarket applications were due.

61. The FDA has shifted the premarket application deadline for deemed products numerous times since August 2016 and is currently set for May 11, 2020.[26]

62. The FDA has explicitly permitted the marketing of ENDS products, as a "special rule" in the TCA prohibiting characterizing flavors other than tobacco and menthol as only applying to cigarettes.[27] In March 2018, the FDA published an Advanced Notice of Proposed Rulemaking, 83 Fed Reg 12994 (Mar. 21, 2018), which solicited the submission of studies, information and public comments regarding the role of flavors in tobacco products, including ENDS products. More recently, the FDA announced that it would soon be finalizing a Guidance Document potentially revising the current compliance policy for non-tobacco flavored ENDS products established by the Maryland District Court.[28]

63. Beyond the FDA, ENDS products are also subject to a number of federal requirements including, among other things, child-resistant packaging under the Child

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[26] The May 11, 2020 compliance deadline was judicially-established in *AmericanAcademyof PediatricsvFoodandDrugAdmin,* No8:18-cv-00883-PWG(D. Md. 2019). Therein, the Maryland District Court ruled the FDA violated the Administrative Procedures Act in adjusting compliance deadlines by way of guidance documents instead of a public and formal comment process.

[27] 21 USC § 387g(a)(l)(A).

[28] Food and Drug Administration, Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products, Press Release (September 11, 2019), available at <https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non> (accessed September 74, 2019).

Nicotine Poison Prevention Act, as administered by the Consumer Product Safety Commission, numerous environmental and hazardous waste disposal laws, as well as false and misleading advertising and marketing restrictions under Section 5 of the Federal Trade Commission Act.[29]

ENDS Distribution And Retail Channels

64. Closed system ENDS products, which presently occupy approximately fifty-eight percent (58%) of the total United States market, are typically distributed and sold through established general retail channels where consumers tend to buy cigarettes and other combustible tobacco products, like gas stations, convenience stores, groceries and pharmacies.

65. Accordingly, closed system ENDS product manufacturers generally either utilize direct distribution to national chain retailers or through existing tobacco distributors.

66. On the other hand, the advent of the open system ENDS products led to the establishment of wholesale distribution businesses, such as OPMH, and independently owned brick-and-mortar retail stores, such as the Plaintiffs, colloquially known as "vape shops". This the case because those consumers using the early versions of open system ENDS products saw new business opportunities as the open system segment grew and expanded.

67. Open system ENDS product wholesale distributors have contractual

[29] Food and Drug Administration, Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products, Press Release (September 11, 2019), available at <https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non> (accessed September 27, 2019).

relationships with manufacturers and typically supply ENDS products to multiple vape shops either regionally or nationally. This enables open system ENDS product manufacturers to have ready access to a wide number of retail customers.

68. In turn, vape shops serve as a hub where ENDS product consumers not only purchase open system ENDS devices and e-liquids, but also seek advice and guidance on using this emerging technology. It is common that employees of vape shops are themselves ENDS product consumers who are well-versed in the many facets of the technology.

69. It is verily believed that presently more than 10,000 brick-and-mortar vape shops across the United States,[30] with at least 300 of these shops operating in Massachusetts. These domestic vape shops are owned by Massachusetts residents, employ Massachusetts residents and largely serve Massachusetts consumers.

70. Massachusetts consumers have benefited from the growth of the vaping industry, as scientific studies indicate that ENDS products do not pose the same health risks as traditional cigarettes and are substantially less harmful.

71. As such, scientific studies show that ENDS products can serve the purpose as tobacco harm reduction products that help consumers avoid the significant health hazards associated with combustible tobacco products. Indeed, recent survey results show that smokers largely turn to ENDS products to improve their health, with the primary goal by reducing or ultimately ceasing their smoking habit.

ENDS Retail Customers

72. It is estimated that approximately 10 million American adults presently

[30] See The Value of Vapor, Guerilla Economics, available at <http://vta.guerrillaeconomics.net/> (accessed September 27, 2019).

use ENDS products,[31] and this number has continued to grow as annual smoking rates among American adults has fallen. To this point, approximately 3.8 million Americans have stopped the use of all tobacco because of ENDS products.

73. Many ENDS product consumers have previously made multiple unsuccessful attempts to stop smoking, including attempts utilizing FDA-approved smoking cessation drugs and other smoking cessation programs. For many smokers, ENDS products have proven to be their last option and the only means of attaining a successful smoking cessation experience.

74. Moreover, the availability of e-liquid ENDS products may not be the predominant factor underlying the recent increase in youth experimentation. The sudden surge in past-30-day use in minors observed in 2018 coincided not with the introduction of flavored ENDS products, which have always been available,[32] but with the

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[31] See Mirbolouk, *et al, Prevalence and Distribution of E-Cigarette Use Among US Adults: Behavioral Risk Factor Surveillance System,* 2016, Ann Intern Med. 2018;169(7):429-438 (October 2, 2018), available at<https://annals.org/aim/article-abstract/2698112/prevalence-distribution-e-cigarette-use-among-u-s-adults-behavioral> (accessed September 27, 2019).

[32] See Amelia Howard, Flavors make vaping more palatable, help cigarette smokers kick the habit, The Inquirer (September 21,2019). <https://www.inquirer.com/opinion/commentary /vaping-flavor-e-cigarettes-teen-smoking- 20190921.html?outputType=amp&_twitter_impression=true> (accessed September 27, 2019). ("Importantly, youth vaping didn't peak at the same time flavor options did. The vape flavor market expanded until 2016, after which the FDA prohibited new products from being introduced without marketing approval. There were an estimated 7,764 flavors available one- cigarette brand websites in 2013. By 2016 that estimate had more than doubled to 15,586. If flavors cause youth to vape, we'd expect youth vaping to have increased steadily with the proliferation of flavors. CDC data show vaping rates among youth increased every year between 2011 (when the behavior was first measured) and 2015. But in 2016, right when the United States vaping market reached "peak flavor," national data showed youth vaping decline for the first time. This low rate remained stable in 2017. Increases in 2018 and 2019 happened when the flavor market was frozen in its 2016 state.") See also Thomas Farley, Pro/Con: As vaping-related illnesses rise, should flavored e-cigarettes be banned? Opinion, The Inquirer (September 21, 2019), <https://www.inquirer.com/opinion/commentary/vaping-flavor-e-cigarettes-teen-

introduction of high-concentration nicotine-salt based "pod-system" ENDS products (like the Juul)[33] which gained access to the convenience store distribution network normally reserved for legacy tobacco products.[34]

75. The FDA has suggested that "open-tank" (*i.e*. open system) ENDS products are ***not*** the source of rising underage use.[35] Open system products are primarily sold in independent adult-only vape shops, rather than in the non-adult-only convenience stores, pharmacies and gas stations where closed system ENDS products are traditionally marketed and sold. It is therefore not surprising that these closed system ENDS product retailers represent the majority of the FDA retailer warning letters and No Tobacco Sale Orders for illegal sales to minors.[36]

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smoking20190921.html?outputType=amp&_twitter_impression=true> (accessed September 27, 2019).

[33] While Juul is available in a handful of non-tobacco and non-menthol flavored pods, what is unique about thee-liquid used in the product is the high concentration (*i.e*., up to 50 mg) of protonated nicotine, commonly referred to as nicotine salts, in its pre-filled pods. It is this high level of nicotine salt in the Juul which creates the "powerful buzz" that drives repeated use, rather than its flavors. See Haley Egle, *Juul nicotine hit may be 'Worst for kids, best for smokers',* WISN ABC (Apr. 29, 2019, 11:32 AM), <https://www.wisn.com/amp/article/juul-nicotine-hit-may-be-worst-for-kids-best-for-smokers/27293019?fbclid=IwAR0xF2TgLNSHUB2DZDIY30gJ0whezaREGoRMXjWg4cJ9vwpoPHpT4uwVV4k> (accessed September 27, 2019).

[34] A review of Nielson data from 2017-18 indicates that the reported surge in underage e-cigarette use corresponds almost exactly with JUUL's rise to dominance of the convenience store channel. See Bonnie Herzog, Nielsen: C-Store Data Through 1/27/18, 2/24/18, and 10/6/18; WELLS FARGO SECURITIES.

[35] U.S. Food and Drug Administration, Statement from FDA Commissioner Scott Gotlieb, MD., on new steps to address epidemic of youth e-cigarette use, (September 12, 2018)" <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm> (accessed September 27, 2019).

[36] U.S. Food and Drug Administration, FDA pursues order barring specific retailers from selling tobacco products as part of its continuing efforts to target youth tobacco use (February 7, 2019): <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm630913.htm?utm_sour

Population Benefits And Youth Concern

76. The national adult smoking rate was approximately 19.8% at the time ENDS products were first marketed in the United States more than a decade ago. Since then, the national adult smoking rate has continued to fall dramatically to an all-time low of 14% by 2018.[37] The recent National Survey on Drug Use and Health determined that the accelerated decline in smoking observed over the last several years is likely attributable to smokers switching to vapor products.[38]

77. A Georgetown University study determined that switching from traditional cigarettes to ENDS products would prevent between 1.6 million and 6.6 million premature deaths over ten years in the United States alone.[39] Thus, lives have been saved, and are being saved, both around the world and in New York as a result of cigarette smokers switching to ENDS products.

78. Massachusetts currently has one of the highest smoking rates in the country as many adults still smoke cigarettes resulting in approximately thousands of annual deaths. Thus, it is cigarette smoking-not flavored vapor products-that poses a public health crisis in Massachusetts.

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ce=Eloqua&utm_medium=email&utm_term=stratcomms&utm_content=pressrelease&utm_cam paign=CTP%20News%3A%20NTSO%20-%202619> (accessed September 27, 2019).

[37] See Smoking rate in US hits all-time low, CDC says, CBS News (June 19, 2018) available at <https://www.cbsnews.com/news/smoking-rate-in-u-s-hits-all-time-low/?> (accessed September 27, 2019).

[38] See Jacob Sullum, Vaping May Be Driving Down Smoking, Says Federal Survey Report, Reason (August 21, 2019), <https://reason.com/2019/08/21/vaping-may-be-driving-down
smoking-says-federal-survey-report/> (accessed September 27, 2019).

[39] See Levy DT, Borland R, Lindblom EN, et al., Potential deaths averted in USA by replacing cigarettes withe-cigarettes, Tobacco Control 2018; 27:18-25 (January 27, 2018), available at <https://tobaccocontrol.bmj.com/content/27/1/18> (accessed September 27, 2019).

79. Prior to the summer of 2019, ENDS products had been available to United States consumers for approximately a decade. During the time, the Plaintiffs verily assert there had not been a single death in the United States attributable to adverse health problems resulting from the use of ENDS products.

80. Beginning in the summer of 2019, numerous media reports began circulating that individuals across the United States who vaped were suffering from severe pulmonary issues, colloquially termed as "vaping related" illnesses.

81. While federal and state health officials initially cast blame upon ENDS products, subsequent investigation and testing of the suspected products used by these individuals revealed that most likely the result of the severe pulmonary issues was the illicit addition of delta-9 tetrahydrocannabinol (THC) and/or marijuana.[40]

82. Neither THC and/or marijuana are included as ingredients of any ENDS product presently registered with the FDA or permitted for retail sale in the United State under federal law. Nevertheless, some consumers add their own aftermarket oils to ENDS products, including THC and/or marijuana.[41]

83. The illegal vapor cartridges that contain THC and/or marijuana have also been reported to contain significant amounts of vitamin E acetate, which is a diluting and thickening agent that makes cannabis oil more affordable.[42]

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[40] Michelle Minton, Update: Big Picture in 'Vaping-Linked' Lung Poisonings, Competitive Enterprise Institute (September 16, 2019), available at <https://cei.org/blog/update-big-picture- vaping-linked-lung-poisonings> (accessed September 27,2019).

[41] Lena Sun, *What we know about mysterious vaping linked illnesses,* The Washington Post (September 7, 2019), at <https://www.washingtonpost.com/health/2019/09/07/what-we-know-
about-mysterious-vaping-linked-illnesses-deaths/> (accessed September 27, 2019).

[42] Paige Minfield Cunningham, The Health 202: Vaping illnesses sparked the e-cig

84. In most cases of reported pulmonary illnesses, health authorities have found vitamin E acetate residue in the patients' lungs. The current scientific thinking is that the vitamin E acetate and other oils contained in these altered products might not completely transform into vapor when heated, and instead travel into the user's lungs thus causing pulmonary disorders.[43]

85. These aftermarket THC and/or marijuana oils and the cutting agents are illegal under federal law as well as the laws of many states, are purchased on the black market and are not available for sale at regulated vapor shops.[44]

86. In fact, the Department confirmed in a press release issued on September 5, 2019 that it had received 34 reports of severe pulmonary illnesses in New York attributable to patients using "at least one cannabis-containing vaping product". The Department disclosed that laboratory testing found "very high levels of vitamin E acetate in nearly all cannabis-containing samples." The Department's press release concluded that the it was focusing upon vitamin E acetate as the potential cause of the reported pulmonary illnesses.[45]

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crackdown. But marijuana is likely to blame, The Washington Post (September 18, 2019), at <https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/20l 9/09/18/the- health-202-vaping-illnesses-sparked-the-e-cig-crackdown-but-marijuana-is-likely-to- blame/5d812a6a88e0fa7bb93a8b9c/> (accessed September 27, 2019).

[43] *Id*.

[44] Jayne O'Donnell, Sketchy THC vape products. Sneaky teens. How patchwork regulations on e-cigarettes led to health crisis, USA Today (September 23, 2019), at <https://www.usatoday.com/story/news/health/2019/09/23/vaping-illnesses-crisis-teens-black-market-thc-no-regulation/2209009001/> (accessed September 27, 2019).

[45] <https://health.ny.gov/press/releases/2019/2019-09-05_vaping.htm> (accessed September 27, 2019).

The Declaration And The Ban

87. On September 24, 2019, Governor Baker issued the Declaration. Governor Baker ordered that the Declaration and the Ban were effective immediately. See Governor's Declaration of Emergency, attached hereto as Exhibit 1.

88. On September 24, 2019, the Commissioner published a letter styled, "Order Of The Commissioner Of Public Health Pursuant To The Governor's September 24, 2019 Declaration Of A Public Health Emergency (Temporary Ban on Sale or Display of Vaping Products)" (the "Commissioner's Order"). See Commissioner's Order, attached hereto as Exhibit 2.

89. The terms of the Declaration and the Commissioner's Order are, in part, as follows:

> The sale or display of all vaping products to consumers in retail establishments, online, and through any other means, including all non-flavored and flavored vaping products, including mint and menthol, including tetrahydrocannabinol (THC) and any other cannabinoid, is prohibited in the Commonwealth.

See Ex.1; see also Ex. 2.

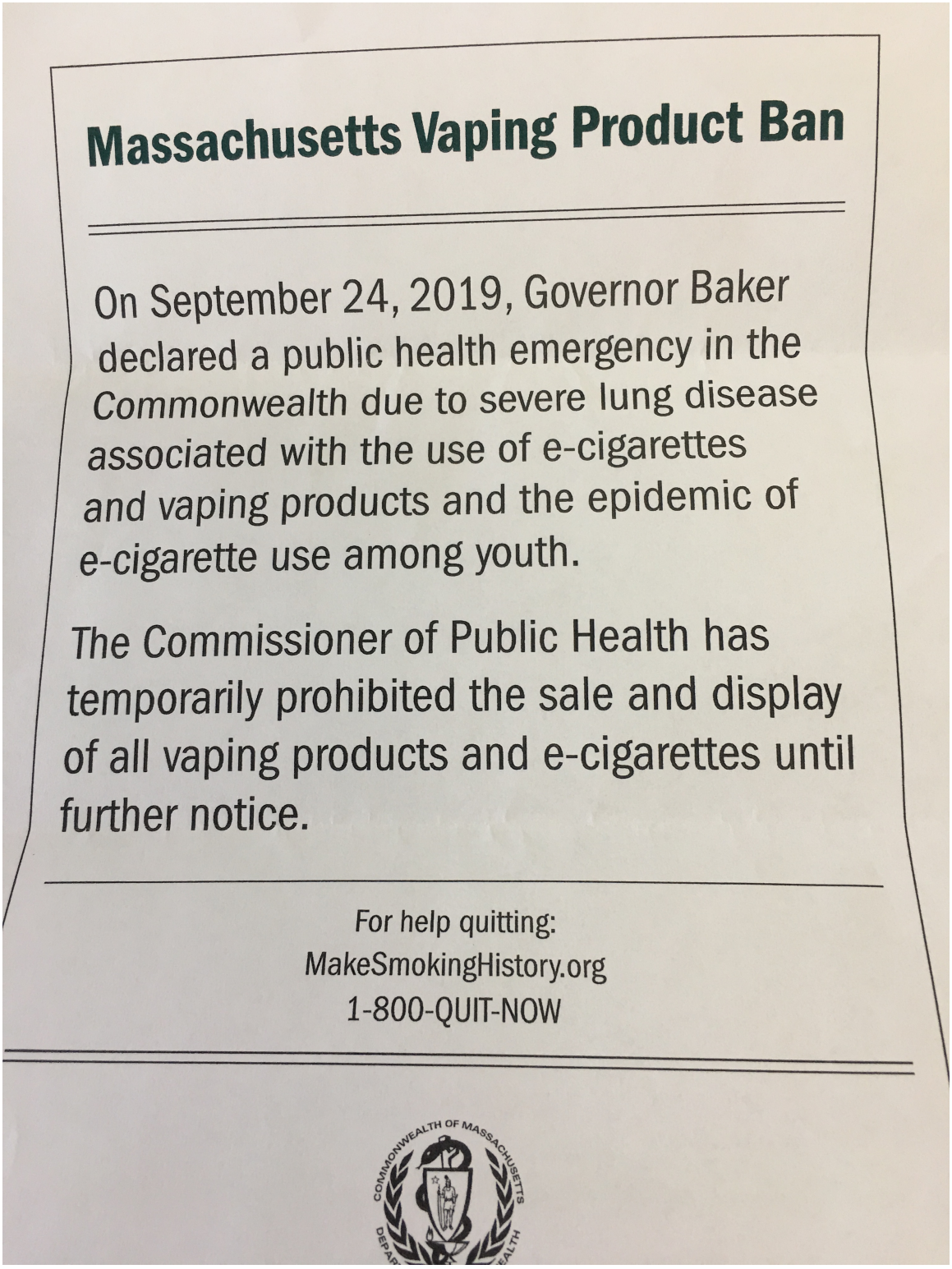
The Signage Regulation

90. On or around September 25, 2019, local boards of health forwarded letters to all businesses with permits to sell tobacco products, including ENDS and e-liquids. See Board of Health Letter, attached hereto as exhibit 3.

91. Pursuant to the Commissioner's Order, and the letters from the boards of health, ENDS and e-liquid retailers were required to remove signage and displays related to ENDS and e-liquids products from their stores.

92. In addition, the Defendants required the Plaintiffs to publish a sign issued

by the Commonwealth warns against the dangers of ENDS products and e-liquids. The following is a depiction of the signage:



93. Failure to post the required signage constitutes a violation of the Ban.

The Need For Prompt Judicial Intervention

94. The Defendants' actions will cause real and irreparable harm for the Plaintiffs, their customers, their vendors, their landlords, their employees and their families. The Plaintiffs are losing, on average, $4,000-$5,000 per week, per store, as a result of the Ban. They will likely have to layoff workers and close their shops if the Ban is not lifted.

95. Without access to ENDS products and e-liquids that are approved and regulated will be forced to return to smoking cigarettes or obtain unregulated ENDS products and e-liquids by other means.

96. The United States Center for Disease Control ("CDC") has stated that illegal, unregulated products have caused the majority of the 805 suspected cases of illness nationwide.

97. All of the products sold by the Plaintiffs are regulated by the FDA and certified by laboratories according to FDA standards.

98. The Plaintiffs have invested substantial time and money into building their business.

99. The Plaintiffs and their employees rely on the revenue generated by the sales of ENDS products and e-liquids to meet the demands of daily living, including, but not limited to, the purchase of gas, groceries, rent and mortgage payments, car payments, daycare, & c.

100. After the imposition of the Ban, the Plaintiffs have not been able to benefit from the revenue from the sale of ENDS products and e-liquids. Thus, the Plaintiffs are unable to direct such revenue towards the payments of rent, groceries, gas and daycare.

101. The Ban will cause the Plaintiffs financial loss and irreparable harm.

CAUSES OF ACTION

COUNT I
(Violation of Commerce Clause)

102. The Plaintiffs reallege, reassert, and incorporate by reference herein each of the allegations contained in paragraphs 1 through 101 of this Amended Complaint as though set forth fully herein.

103. Article I, Section 8 of the United States Constitution grants to Congress the exclusive authority to regulate interstate commerce. Under the Dormant Commerce Clause, the several states are precluded from applying a statute or a regulation so that it governs commerce taking place outside of the state, or which otherwise controls conduct beyond the boundaries of the state. A state statute or regulation that results in extraterritorial regulation of interstate commerce is *per se* unconstitutional.

104. The terms of the Declaration and the Ban, as described in the Commissioner's Order, provide that the sale or display of ENDS products and e-liquids to consumers in retail establishments, online and through any other means is prohibited in the Commonwealth. See Ex. 2.

105. The Ban, however, does not limit its applicability to only Massachusetts transactions or activity. The sweeping language found in the Commissioner's Order and the Governor's Declaration means that in-state manufacturers, distributors and retailers are not only prohibited from selling such products to Massachusetts customers, but are

also prohibited from selling such products to consumers located in other states. In fact, in-state manufacturers, distributors and retailers cannot even maintain a stock of ENDS products and e-liquids during the pendency of the Ban, because many are perishable.

106. The Plaintiffs purchase ENDS products and e-liquids from in-state and out-of-state manufacturers wholesalers, and sell the same to in-state and out-of-state customers.

107. The Plaintiffs market ENDS products and e-liquids on the Internet which can be accessed by customers outside of the Commonwealth of Massachusetts.

108. The Commissioner's Order, the Governor's Declaration and the Bann have the effect of regulating the content of the websites operated by the Plaintiffs', and others, as such content is streamed in other states. To comply with these marketing restrictions, in-state manufacturers, distributors and retailers, including the Plaintiffs, must either remove all images of e-liquid ENDS products, all product descriptions, pricing information and purchase portals from their websites, all of which means such information cannot be seen by consumers and customers located in other states, or risk and enforcement action.

109. The Commissioner's Order, the Governor's Declaration and the Ban thus projects the Commonwealth's policy choices regarding e-liquids and ENDS products on other states that might take a different regulatory approach. By preventing in-state manufacturers, distributors and retailers, including the Plaintiffs, from engaging in sales and marketing activities in other states, Massachusetts will substantially alter the flow of goods across state borders. Moreover, Massachusetts will project is ban on ENDS products and e-liquids into other states, even those that have adopted public health

policies of maximizing adult consumer access to flavored e-liquid ENDS products so that they can move away from their smoking habits.

110. Based on the Commissioner's Order and the Governor's Declaration, the Ban imposes burdens on interstate commerce which are clearly excessive in relation to any putative local benefits.

111. In-state manufacturers, distributors and retailers who violate these unconstitutional provisions are subject to extensive civil and criminal penalties. See Ex. 2. The Plaintiffs have accordingly suffered, or will suffer, substantial and tangible harm from the impermissible and unconstitutional actions described above.

112. The Declaration, the Ban and the Commissioner's Order violate the Commerce Clause to the United States Constitution and its corollary prohibition on extraterritorial regulation. Thus, the subject provisions should be declared unconstitutional and the Defendants be permanently enjoined from the enforcement thereof in their entirety as to manufacturers, distributors and retailers with respect to the sale of e-liquid ENDS products outside the Commonwealth of Massachusetts.

WHEREFORE, the Plaintiffs request that this Court enter an Order vacating the Declaration, preventing the enforcement of the Ban, issuing injunctive relief, awarding the Plaintiffs monetary damages for lost business income and reasonable attorneys' fees and costs, and any other such relief as this Court deems just and fair.

COUNT II
(Violation of First Amendment of the United States Constitution)

113. The Plaintiffs reallege, reassert, and incorporate by reference herein each of the allegations contained in paragraphs 1 through 112 of this Amended Complaint as though set forth fully herein.

114. The First Amendment, applicable to the States through the Fourteenth Amendment, prohibits the enactment of laws "abridging the freedom of speech." U.S. Const. Amdt. 1; see also Reed v. Town of Gilbert, 135 S.Ct. 2218 (2015).

115. The Ban prohibits ENDS manufacturers, retailers and distributors, including the Plaintiffs, from marketing or advertising ENDS products and e-liquids, among other places, in their stores and on their websites.

116. The Commissioner's Order also requires ENDS products and e-liquid retailers, including the Plaintiffs, to display signage that states that the severe lung disease is associated with ENDS products and e-liquids.

117. The prohibition on marketing or advertising ENDS products and e-liquids, and the Signage Regulation, abridges the Plaintiffs' freedom of speech.

118. Accordingly, the Governor's Declaration, the Ban, the Commissioner's Order and the Signage Regulation violate the First Amendment to the United States Constitution and should be declared void and unconstitutional.

WHEREFORE, the Plaintiffs request that this Court enter an Order vacating the Declaration, preventing the enforcement of the Ban, issuing injunctive relief, awarding the Plaintiffs monetary damages and reasonable attorneys' fees and costs, and any other such relief as this Court deems just and fair.

COUNT III
(Violation Of Supremacy Clause As To Signage Regulation)

119. The Plaintiffs reallege, reassert, and incorporate by reference herein each of the allegations contained in paragraphs 1 through 118 of this Amended Complaint as though set forth fully herein.

120. Article VI, Clause 2 of the United States Constitution declares "the Laws of the United States … shall be the supreme law of the land." Under the Supremacy Clause, federal law preempts state law when: (i) a federal statute does so "expressly" ("express preemption"); or, (ii) where the state statute prevents "the accomplishment and execution of the full purposes and objectives" of federal law ("obstacle preemption").

121. The TCA expressly preempts any state laws that regulate "labeling" and "modified risk tobacco products" ("MRTP") in a manner that is "different from or in addition to" federal regulation under the TCA. See 21 U.S.C. § 387p(a)(2)(A).

122. The TCA's MRTP provision prohibits ENDS product manufacturers, retailers and distributors, including the Plaintiffs, from making claims in their labeling or advertising that an ENDS product, among other things, contains or does not contain a certain substance. The FDA may grant approval of the MRTP claims of an END product manufacturer, distributor, or retailer after an extensive review of product data and information. See 21 U.S.C. § 387k(b).

123. The Signage Regulation requires ENDS product retailers to display language that contains the statement, "severe lung disease [is] associated with the use of e-cigarettes and vaping products." The Signage Requirement thus requires ENDS product retailers, including the Plaintiffs, to make affirmative statements about the content of certain substances contained in the ENDS products they sell. Accordingly, the Signage Requirement forces the Plaintiffs to either violate the TCA and Deeming Rule, or violate the Signage Requirement.

124. As such, the Signage Requirement is pre-empted by the TCA and Deeming Rule and should be declared void and unconstitutional.

WHEREFORE, the Plaintiffs request that this Court enter an Order vacating the Declaration, preventing the enforcement of the Ban, issuing injunctive relief, awarding the Plaintiffs monetary damages and reasonable attorneys' fees and costs, and any other such relief as this Court deems just and fair.

COUNT IV
(United States Constitution: Contract Clause)

125. The Plaintiffs reallege, reassert, and incorporate by reference herein each of the allegations contained in paragraph 1 through 124 of this Complaint, as though set forth fully herein.

126. The Contract Clause of the United States Constitution provides that no state shall pass any law "impairing the obligations of contracts." U.S. CONST. art. I, § 10, cl. 1.

127. The Ban broadly bans the marketing and sale of ENDS products and e-liquids in the Commonwealth of Massachusetts.

128. The Plaintiffs have valid contracts with wholesalers who supply ENDS products and e-liquids to retailers in the Commonwealth of Massachusetts. Because the subject matter has become illegal under the Ban, these contracts between the Plaintiffs and their wholesalers are now substantially impaired. The Ban also will impair the Plaintiffs ability to make payments to these wholesalers.

129. The Plaintiffs also have contracts with landlords for the rental of their shop's retail spaces. The Ban irretrievably frustrates the purpose of the lease agreements and impairs the Plaintiffs ability to receive the benefits for which they bargained for.

130. For the reasons set forth herein, the Ban does not reflect a significant and legitimate public purpose. The Defendants have not appropriately explained the contours

of a public emergency necessitating the drastic step it has taken. Furthermore, it applies only to ban ENDS products and e-liquids while ignoring the unique advantages of ENDS products and e-liquids to other tobacco products, which are also regulated by FDA pursuant to the FDCA and the TCA.

131. For the reasons set forth herein, the Ban is not based upon reasonable conditions and is not of a character appropriate to the Defendants' stated public purpose. The Ban is *ultra vires* and could never be adequately tailored, to the extent that the Defendants lack authority to issue the Declaration and Ban in the first place. Moreover, it is too grossly under- and over-inclusive to reflect any level of tailoring, on its own terms.

132. The Plaintiffs have no adequate remedy at law for the violation of the Contracts Clause.

133. The Ban will cause substantial, imminent, and irreparable injury to the Plaintiffs unless the Declaration is vacated and the Defendants are enjoined from enforcing the Ban.

WHEREFORE, the Plaintiffs request that this Court enter an Order vacating the Declaration, preventing the enforcement of the Ban, issuing injunctive relief, awarding the Plaintiffs monetary damages and reasonable attorneys' fees and costs, and any other such relief as this Court deems just and fair.

COUNT V
(United States Constitution: Regulatory Taking)

134. The Plaintiffs reallege, reassert, and incorporate by reference herein each of the allegations contained in paragraphs 1 through 133 of this Complaint as though set forth fully herein.

135. The Fifth and Fourteenth Amendments to the United States Constitution prevent the Commonwealth of Massachusetts from taking private property without just compensation. U.S. CONST. Fifth Amendment, Fourteenth Amendment.

136. The issue of regulatory takings arises from the interaction between the exercise of traditional police power and the exercise of eminent domain. However, when the regulation goes too far, it will be judicially recognized as the equivalent of a taking which may not take place without payment of just compensation to the property's owner.

137. Here, the Declaration has gone too far because it is arbitrary and capricious, and the Ban has gone too far because it has denied the Plaintiffs the fundamental due process ingredients of notice and opportunity.

138. The Defendants have also violated the Supremacy Clause, the Contracts Clause and the Commerce Clause of the United States Constitution by issuing the Declaration and enforcing the Ban.

139. The Ban will cause substantial, imminent and irreparable harm to the Plaintiffs unless the Declaration is vacated and the Defendants are enjoined from enforcing the Ban.

WHEREFORE, the Plaintiffs request that this Court enter an Order vacating the Declaration, preventing the enforcement of the Ban, issuing injunctive relief, awarding the Plaintiffs monetary damages and reasonable attorneys' fees and costs, and any other such relief as this Court deems just and fair.

COUNT VI
(Violation of 42 U.S.C. 1983)

140. The Plaintiffs reallege, reassert, and incorporate by reference herein each of the allegations contained in paragraphs 1 through 139 of this Complaint as though set forth fully herein.

141. 42 U.S.C. § 1983 prohibits the deprivation of any rights, privileges, or immunities secured by the Constitution and laws.

142. The Defendants have violated 42 U.S.C. § 1983 by depriving the Plaintiffs' of their rights under the Supremacy Clause, the Contracts Clause, the Commerce Clause of the United States Constitution, and the Fifth and Fourteenth Amendments of the same by issuing the Declaration and enforcing the Ban, as described is this Complaint.

143. The Ban will cause substantial, imminent and irreparable harm to the Plaintiffs unless the Declaration is vacated and the Defendants are enjoined from enforcing the Ban.

WHEREFORE, the Plaintiffs request that this Court enter an Order vacating the Declaration, preventing the enforcement of the Ban, issuing injunctive relief, awarding the Plaintiffs monetary damages and reasonable attorneys' fees and costs, and any other such relief as this Court deems just and fair.

COUNT VII
(Declaratory Judgment: M.G.L. c. 17, § 2A)

144. The Plaintiffs reallege, reassert, and incorporate by reference herein each of the allegations contained in paragraphs 1 through 143 of this Complaint as though set forth fully herein.

145. An actual controversy, within the meaning of 28 U.S.C. §§ 2201-2202, that is capable of judicial resolution exists between the parties as to whether the Declaration and the Ban are constitutional and enforceable by the Defendants.

146. The Plaintiffs are entitled to a declaratory judgment that the Declaration must be vacated, because it was issued in an arbitrary and capricious manner, thereby violating the Governor's authority to issue the Declaration.

147. The Plaintiffs claim that the Governor's Declaration, the Ban and the Commissioner's Order violate the Dormant Commerce Clause, the Contracts Clause, the First Amendment, the Fifth Amendment and the prohibition on extraterritorial regulation, and is unconstitutionally overbroad. The Plaintiffs also claim that the Signage Regulation violates the Supremacy Clause of the United States Constitution because it is preempted under the Federal TCA and FDA's regulation.

148. The Plaintiffs are entitled to a declaratory judgment that the Governor's Declaration is vacated, and that the enforcement of the Ban is a violation of the Defendants' authority.

WHEREFORE, the Plaintiffs request that this Court enter an Order vacating the Declaration, preventing the enforcement of the Ban, issuing injunctive relief, awarding the Plaintiffs monetary damages and reasonable attorneys' fees and costs, and any other such relief as this Court deems just and fair.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs respectfully pray for the following relief:

A. A declaration pursuant to 28 U.S.C. § 2201 that the Governor's and Commissioner's conduct in effectuating the Ban on ENDS and e-liquids violates the United States Constitution;

B. A declaration that the Defendants violations of the Constitution also constituted a violation of 42 U.S.C. § 1983, and an award of damages pursuant to said statute;

C. Temporary, preliminary and permanent injunctive relief and/or a final order enjoining the Defendants from implementing or enforcing the Declaration, the Ban, or any other action banning the purchase and sale of ENDS products or e-liquids. In the alternative, temporary, preliminary and permanent injunctive relief and/or a final order vacating the Governor's Declaration of Emergency, the Commissioner's Ban, and any other conduct undertaken by or at the direction of the Defendants relating to the Commonwealth's effort to ban ENDS products and e-liquids;

D. An award of costs and expenses, including reasonable attorney's fees against the Commonwealth pursuant to 42 U.S.C. § 1988; and

E. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs respectfully demand a jury trial of any and all issues triable of right before a jury.

Respectfully submitted,

PLAINTIFFS,
MASS DYNAMICS, LCC,
BOSTON VAPOR, LLC,
LINDA AND JEFFREY VICK d/b/a
VICK'S VAPE SHOP,
JIMBUDDY'S INCORPORATED,
and JERALD MOLLMAN d/b/a
J'S VAPOR DEN,
By their attorney,

/s/ Craig E. Rourke

_____

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Dated: October __, 2019

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the above document was filed with the Office of the Civil Clerk for the United States District Court, District of Massachusetts, via electronic means, and will be sent electronically to the Defendants on October __, 2019. Paper copies will be served by hand on the Defendants at the following addresses on October 3, 2019:

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/s/ Craig E. Rourke
Craig E. Rourke

LOCAL RULE 7.1(A)(2) CERTIFICATION AND CERTIFICATE OF SERVICE

I, Craig E. Rourke, hereby certify that Attorney Cheryl Jacques of my office conferred with counsel from the Office of the Massachusetts Attorney General on or around October 1, 2019 in an effort to resolve or narrow the issues presented in this motion prior to filing.

/s/ Craig E. Rourke

Craig E. Rourke